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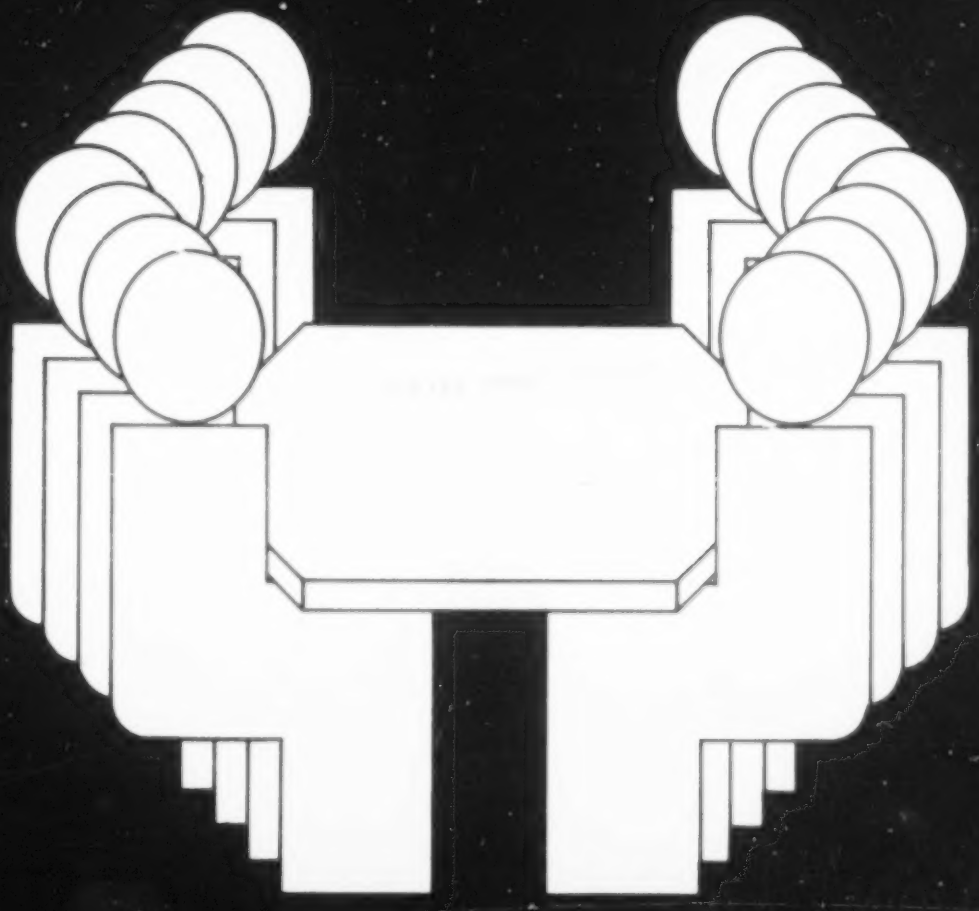
Orientation Handbook For Members of Scientific Review Groups

National Institutes of Health

August 1982



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

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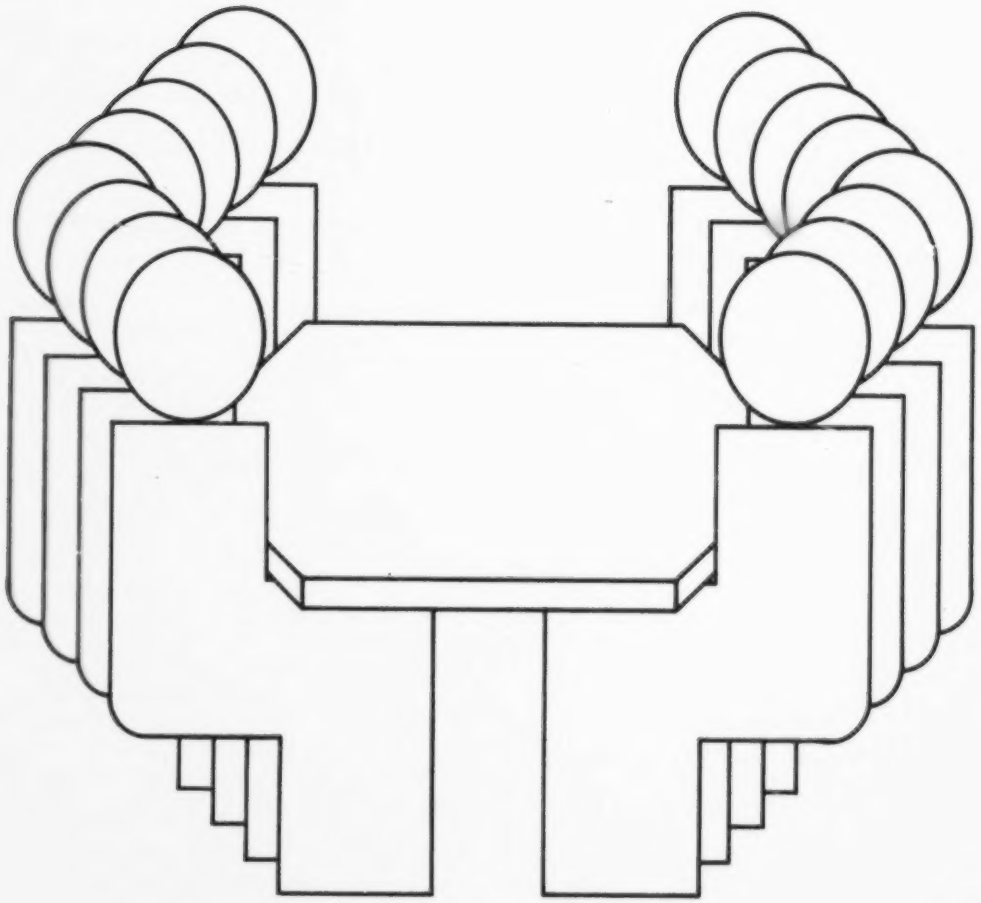

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Abbreviations*

ADERT	Associate Director for Extramural Research and Training, NIH
BID	NIH Bureau, Institute, or Division (Referred to as an "Institute" in this handbook)
CC**	Clinical Center
DHHS	Department of Health and Human Services
DRG**	Division of Research Grants
DRR**	Division of Research Resources
FIC**	Fogarty International Center
IRG	Initial Review Group (Performs initial scientific merit review of grant applications—also called Scientific Review Group)
NCI**	National Cancer Institute
NEI**	National Eye Institute
NHLBI**	National Heart, Lung, and Blood Institute
NIA**	National Institute on Aging
NIADDK**	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
NIAID**	National Institute of Allergy and Infectious Diseases
NICHD**	National Institute of Child Health and Human Development
NIDR**	National Institute of Dental Research
NIEHS**	National Institute of Environmental Health Sciences
NIGMS**	National Institute of General Medical Sciences
NIH	National Institutes of Health
NINCDS**	National Institute of Neurological and Communicative Disorders and Stroke
NLM**	National Library of Medicine
NRSA	National Research Service Award
OD	Office of the Director
OPRR	Office for Protection from Research Risks, OD
ORDA	Office of Recombinant DNA Activities, NIAID
PHS	Public Health Service
RCDA	Research Career Development Award
RFA	Request for Applications (Announcement requesting grant applications for a research area)
RFP	Request for Proposals (Announcement requesting contract proposals for a project)
SRB	Scientific Review Branch (DRG)
SRG	Scientific Review Group (Performs initial scientific merit review of grant applications and contract proposals—called Initial Review Group when pertaining to great applications)

* This list includes abbreviations used in this text as well as those commonly encountered in the review of grant applications and contract proposals.

** The two letter abbreviation used for grant applications and contract proposals can be found in *Activity Codes, Organizational Codes and Definitions used in Extramural Programs*

1. Introduction

Mission of the National Institutes of Health

The mission of the National Institutes of Health (NIH) is to improve the health of the people of the United States by increasing our understanding of the processes underlying human health and by acquiring new knowledge to help prevent, detect, diagnose, and treat disease.

NIH accomplishes this mission by:

- supporting research in universities, medical schools, hospitals, and research institutions in this country and abroad;
- conducting research in its own laboratories and clinics;
- supporting training for promising young researchers;
- helping to develop and maintain research resources;
- identifying research findings that can be applied to the care of patients, and helping to transfer such advances to the health care system;
- promoting effective ways to communicate biomedical information to scientists, health practitioners, and the public; and
- developing and recommending policies related to the conduct and support of biomedical research.

Organization of the NIH

The NIH is comprised of eleven research Institutes, three of which have legislated status as Bureaus, the Division of Research Resources, three service Divisions, a research hospital called the Clinical Center, the National Library of Medicine, and the Fogarty International Center. While most of the NIH is in Bethesda, Maryland, the National Institute of Environmental Health Sciences is located in Research Triangle Park, North Carolina, the Intramural Program of the National Institute on Aging is located in Baltimore, Maryland, and some research components of the NIH are located in other areas of the United States. Figures 1a and 1b show the general organization of the NIH and its position within the Department of Health and Human Services (DHHS).

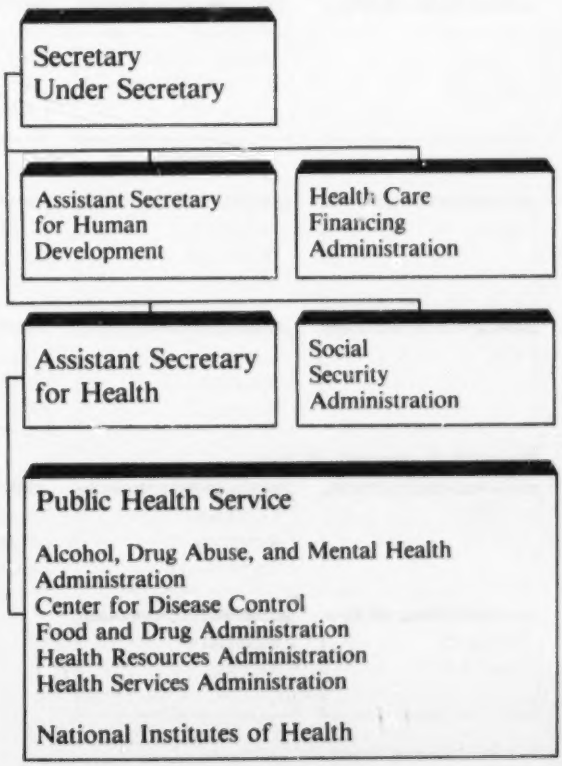
A Typical Institute

Even though there are specific internal variations among the Bureaus, Institutes, or Divisions, all of which are hereafter referred to as "Institutes," a typical organizational pattern exists. Usually, both laboratory and clinical research are conducted directly by an Institute through its intramural program and are sponsored in other research organizations through an extramural program of grants and contracts (Figure 2). An extramural program is organized into specific scientific areas, each of which may provide research funding through grants and contracts.

Extramural Research Support

The diverse mechanisms for extramural research and development are divided into two main categories: grants and contracts. Grants typically support regular research projects, program projects, and centers, as well as other forms of assistance such as individual and institutional fellowship awards and Research Career Development Awards. In general, the investigator who applies for a grant, through an eligible institution, is responsible for developing the ideas, concepts, methods, and approach for

Figure 1a.
Department of Health and Human Services



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a research project. In contrast, the awarding Institute is responsible for establishing the plans, parameters, and detailed requirements for projects that would be supported by contracts. Contracts are often solicited through requests for proposals (RFPs), while most grants are not solicited. In certain circumstances, however, grant applications are invited to support areas of special interest to an awarding unit, in which case requests for applications (RFAs) and program announcements are issued. Other distinctions between contracts and grants involve such technical issues as the cost reimbursement, the timing of the application or proposal process, the requirements and mechanisms for award and administration, the extent of the involvement of the sponsoring Institute, and the delivery of the end product.

Another form of support, called the cooperative agreement, has recently been legislatively mandated. The cooperative agreement, like the grant, is oriented to support or stimulate the recipient's activities, but provides for substantial involvement on the part of the funding agency during the period of performance.

Grant applications are classified according to type, such as new, competing continuation (renewal), and supplemental applications, and according to activities, such as regular research projects, conferences, program projects, centers, and fellowships. The classification of a grant application is indicated by an identification numbering system that appears in the upper right-hand corner of the first page of the standard application (Form PHS 398). Each part of the identification number has a distinct function, which is explained in *Activity Codes, Organizational Codes, and Definitions Used in Extramural Programs,* a Division of Research Grants (DRG) publication that is updated annually and available from the executive secretary of a review group. This publication also describes the classification and numbering system for contracts. Contracts are classified according to transaction types, such as new, renewal, and continuation of incrementally funded contracts.

Figure 1b.
National Institutes of Health

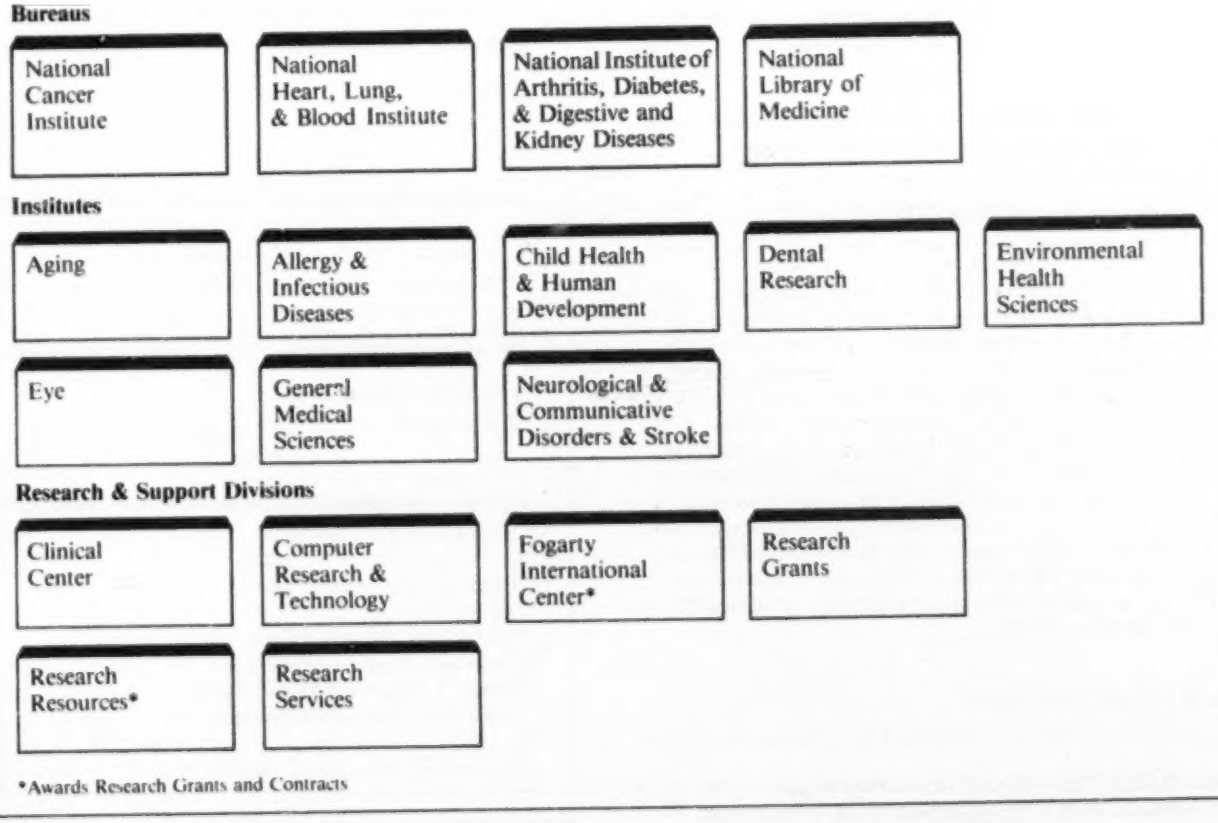
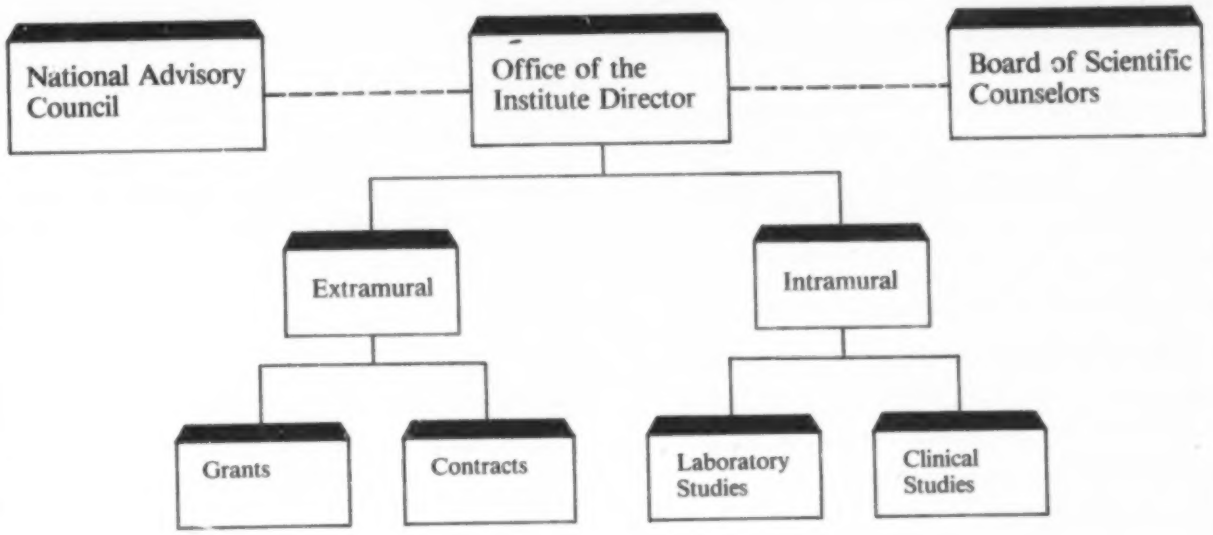


Figure 2.
A Typical Institute



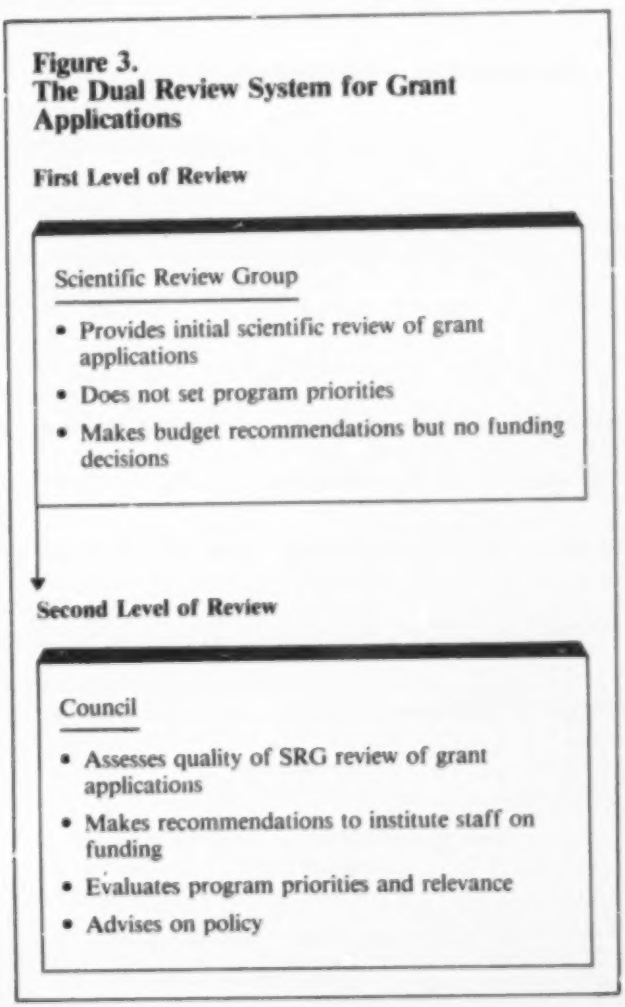
2. The Peer Review System

Because of the magnitude, diversity, and complexity of its research mission, as well as its pursuit of excellence, the NIH draws for assistance on the national pool of scientists actively engaged in research. These scientists assist the NIH by advising on the selection of the most meritorious and the most promising research projects for award.

Dual Review of Grant Applications

The peer review system for grant applications used by the NIH is based on two sequential levels of review, referred to as the "dual review system" (Figure 3). The first level involves panels of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. These panels, which are legislatively mandated, are generally referred to as scientific review groups (SRGs) if they review both grant applications and contract proposals, initial review groups (IRGs) if they review only grant applications. In DRG, the panels are called study sections.

Figure 3.
The Dual Review System for Grant Applications


First Level of Review
Scientific Review Group
• Provides initial scientific review of grant applications
• Does not set program priorities
• Makes budget recommendations but no funding decisions
Second Level of Review
Council
• Assesses quality of SRG review of grant applications
• Makes recommendations to institute staff on funding
• Evaluates program priorities and relevance
• Advises on policy

The second level of review is by a national advisory board or council, hereafter referred to as a "Council," composed of both scientific and lay representatives who are noted for their expertise, interest, or activity in matters related to the mission of the specific Institute on which they serve. Council recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study, as outlined in a grant application, to an Institute's programs and priorities.

The dual review system, which separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, permits a more objective evaluation than would result from a single level of review. The dual system of review provides the responsible NIH officials with the best available advice about scientific as well as societal values and needs. (The publications listed in Appendix A provide more extensive discussions of various aspects of the peer review system used by the NIH.)

Peer Review of Contract Proposals

The peer review process for contract proposals is similar in principle to that for grant applications (Figure 4). A program advisory group, composed largely of non-Federal advisors, first reviews the contract concept to determine whether the anticipated results will be beneficial to the NIH and whether the necessary technology and resources are available. If the contract concept is approved, a formal solicitation document, the RFP, is prepared and advertised to the scientific community.

Proposals in response to the RFP are reviewed for scientific and technical merit by an SRG. The final level of review is by Institute staff, who review the SRG recommendations and carefully consider the proposals' responsiveness to the RFP, program balance, proposed costs, and availability of funds before making a final decision on the award.

The above discussion pertains to solicited contract proposals, but Institutes also occasionally make awards in response to unsolicited contract proposals. In this case, the SRG routinely evaluates the concept and the scientific and technical merit at the same session. The final evaluation process is the same as for solicited contract proposals.

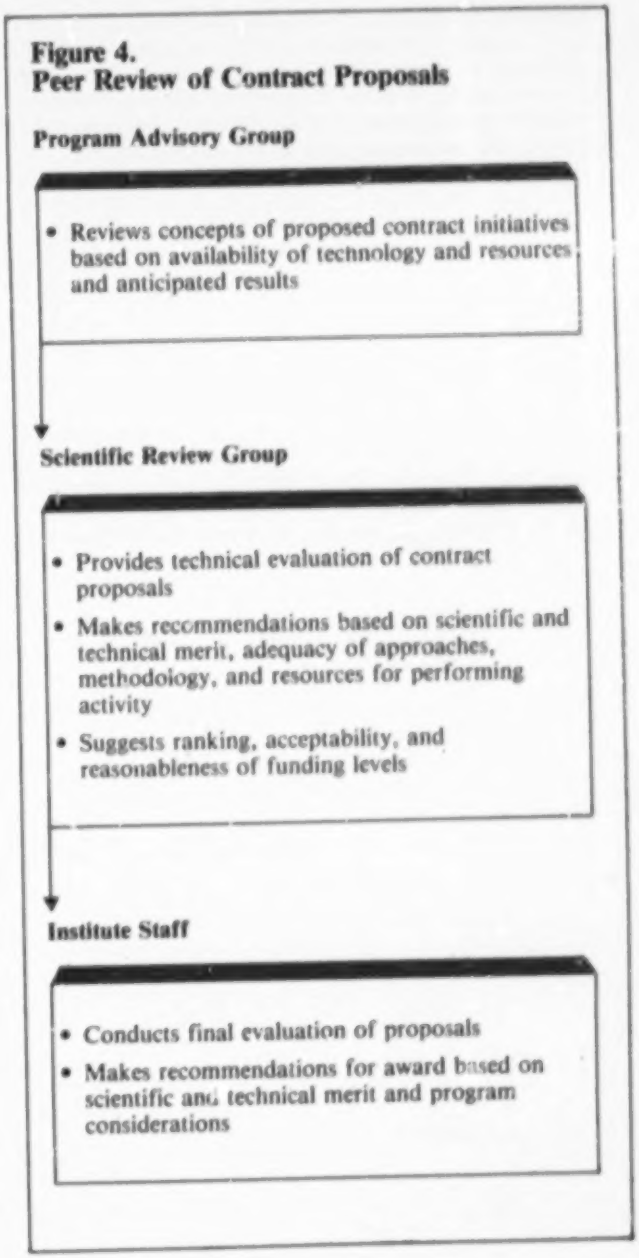
How Members of Scientific Review Groups are Selected

The primary requirement for serving on an SRG is demonstrated competence and achievement as an independent investigator in a scientific or clinical discipline or research specialty. Assessment of such competence is based on the quality of research accomplished, publications in refereed scientific journals, and other significant scientific activities, achievements, and honors. Usually, a doctoral degree or its equivalent is required. Service also requires mature judgment, balanced perspective, objectivity, ability to work effectively in a group context, commitment to work assignments, personal integrity to assure the confidentiality of applications and discussions, and the avoidance of real or potential conflicts of interest.

In addition, factors such as geographic distribution and adequate representation of ethnic minority and women scientists must be considered. Further, no more than one member from the same organization may be appointed to any one advisory group. An interval of one year must occur before a retiring reviewer can be appointed to the same or another NIH committee, and no one may be appointed to serve simultaneously on two chartered DHHS committees. (Exceptions to these restrictions are rare and must be approved by the Committee Management Officer of the DHHS.)

To identify as many potential reviewers as possible, the NIH annually invites suggestions for membership on its SRGs and Councils. These public announcements include explanations about the functions of each group, the expertise or societal considerations required, and the number of anticipated vacancies during the next year. The executive secretaries, who are NIH health scientist administrators in charge of review and advisory groups, nominate candidates from this list, their own knowledge and experience, recommendations of NIH staff and other scientists, and other sources. Final appointment to SRGs and advisory committees is made by the Director, NIH; appointment to Councils is by the Secretary of DHHS. Appointments are for up to 4 years and staggered so that about a fourth of the membership of a group are new each year.

Figure 4.
Peer Review of Contract Proposals


Program Advisory Group
• Reviews concepts of proposed contract initiatives based on availability of technology and resources and anticipated results
Scientific Review Group
• Provides technical evaluation of contract proposals
• Makes recommendations based on scientific and technical merit, adequacy of approaches, methodology, and resources for performing activity
• Suggests ranking, acceptability, and reasonableness of funding levels
Institute Staff
• Conducts final evaluation of proposals
• Makes recommendations for award based on scientific and technical merit and program considerations

Responsibilities of the NIH Staff

As shown in Figure 5, the review, program, and grants and contract management staff of the NIH have important but separate responsibilities in the review, award, and management processes for grants and contracts.

Figure 5.
Responsibilities of NIH Staff in the Review, Award, and Management of Grants and Contracts

Review Staff

- Nominate SRG members
- Select ad hoc reviewers and site visitors
- Provide orientation for SRG members
- Explain and interpret NIH review policies and procedures
- Assign review responsibilities
- Manage project site visits
- Manage SRG meetings
- Prepare summary statements
- Attend Council meetings to provide requested information in support of committee recommendations
- Communicate with program staff on review matters

Program Staff

- Develop program initiatives
- Provide guidance and assistance to applicants
- Interpret program policy and guidelines for reviewers
- Attend SRG meetings as program resource person(s)
- Present SRG recommendations to Council
- Communicate results of review to applicants
- Make award decisions
- Participate in identifying prospective SRG and Council nominees
- Evaluate programs
- Communicate with review staff on program matters
- Monitor research progress during the award period

Grants and Contracts Management Staff

- Provide business guidance to applicants and reviewers as necessary
- Participate with program staff in budget negotiations prior to and following awards
- Attend SRG meetings as resource person(s)
- Maintain official grant and contract files
- Assist in developing program policy
- Provide fiscal management of grants and contracts

3. Review Process: Grant Applications

The review cycle for a grant application begins when an investigator submits an application to the NIH, through an institution that qualifies for NIH grants-in-aid, and concludes when the applicant institution and the principal investigator are notified about the recommendation of the Council (Figure 6).

Within the NIH, the review cycle involves the interaction of the DRG and the appropriate awarding Institute. Organizationally, the DRG is accountable to the Director, NIH, and is separate from the Institutes. The DRG has no responsibilities for either the decisions about funding or the management of grant programs.

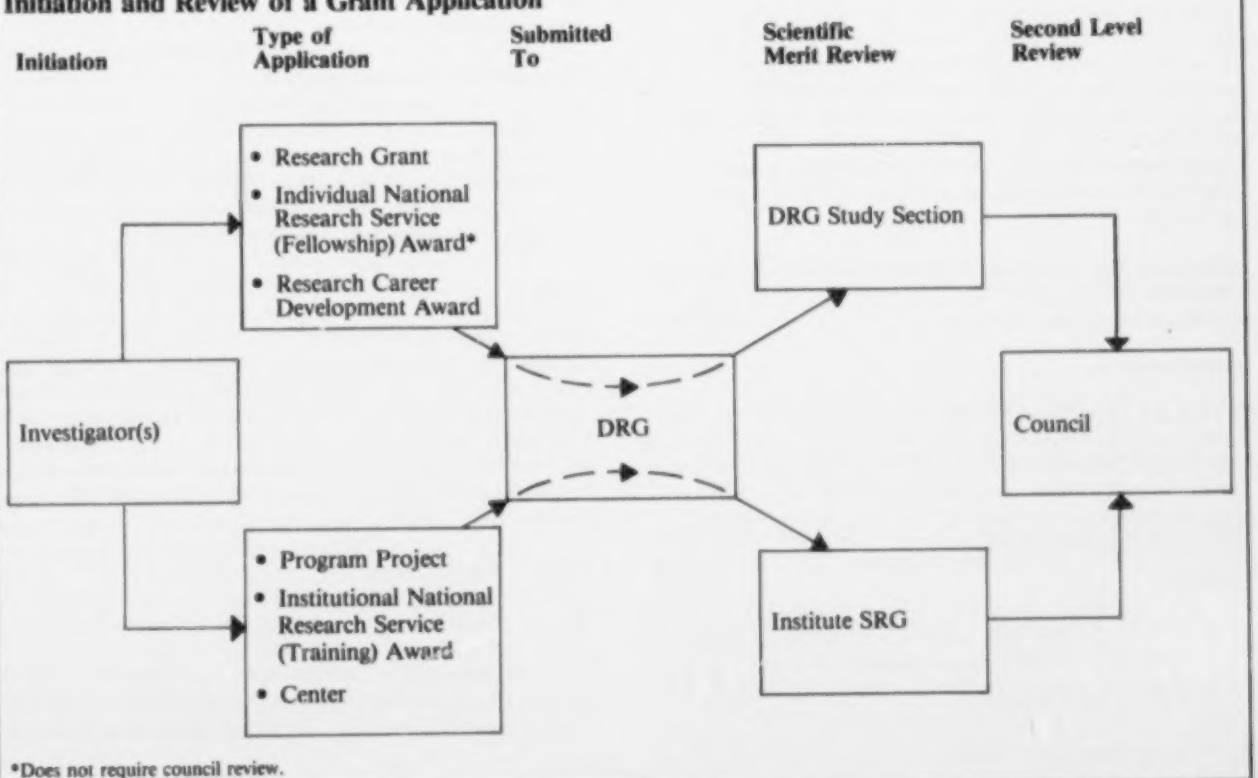
Assignment of Applications for Review and Institute Sponsorship

Grant applications submitted to the NIH are received centrally in the DRG. In the Referral Branch, referral officers, who are health scientist administrators in the DRG, determine the relevance of each application to the overall mission of the NIH and assign acceptable applications to an appropriate SRG and to an appropriate Institute. Assignment to an SRG is based on the complementarity of a proposed research project to the review responsibilities and scientific expertise of the membership of the SRG, while assignment to an Institute is based on the Institute's legislatively mandated program responsibility. If the subject matter of an application is pertinent to the program responsibilities of two Institutes, a dual assignment may be made.

Initial Review by Peers

Depending upon the type of research proposed, the first level or scientific merit review is by an SRG located either within the Scientific Review Branch of the DRG or within an Institute. The study sections in the DRG review most applications for research project grants. The SRGs in the Institutes are usually multidisciplinary and are thus

Figure 6.
Initiation and Review of a Grant Application



*Does not require council review.

constituted to review more complex program project and center grant applications.

The following discussion of the initial review process for the scientific and technical merit of research grant applications contains principles that are common to the review of all grant applications submitted to the NIH. Significant variations in the process for the initial review of some major grant mechanisms, such as research project grants, program project grants, National Research Service Awards, and Research Career Development Awards, are described in subsequent sections.

Reviewers' Preliminary Written Comments

Well in advance of an SRG meeting, the executive secretary sends each member copies of all applications and supporting material to be reviewed at the meeting. Each member is expected to read and become familiar with these applications. The executive secretary also assigns each application to two or more SRG members for detailed written reviews. The designated reviewers lead the discussion of their assigned applications at the meeting of the SRG.

The reviewers' written comments are often the basis for the final recommendation of the SRG and for the summary statement prepared by the executive secretary for transmittal to the appropriate Council and ultimately to the principal investigator. Consequently, the reviewers' comments and the summary statement should be suitable for their intended uses in format, content, and phrasing. Reviewers must provide specific substantiation of their recommendations of approval, disapproval, or deferral. Unexplained abbreviations and laboratory jargon should be avoided.

The following general guidelines are organized around the standard format for preliminary written reviews. Detailed instructions will be provided by each executive secretary.

Description

Prepare a concise description of the proposal, including aims and procedures as appropriate for a clear discussion of the project proposed. In the case of competing continuation (renewal), deferred, or revised applications, include a description of the background. Do not make evaluative statements in this section.

Critique

Evaluate the strengths and weaknesses of the various aspects of the proposal.

- Are the aims logical?
- Is the hypothesis valid?
- Are the procedures feasible and adequate for the research proposal?
- Is the research likely to produce new data and concepts or confirm existing hypotheses?
- What is the significance and originality of the proposed study in its scientific field?

Provide specific examples to document the evaluation, but do not repeat the description. Descriptive phrases meant to be critical have little or no impact, for the implications are not always apparent to those less familiar with the field. For example, the statement that "the investigator will use single agar diffusion to measure antigen concentration" should not be used if you really mean that "the assay method to be employed is not sensitive enough to measure the amount of antigen present." For competing continuation (renewal) and supplemental requests, evaluate past progress. Be sure to address both the strengths and weaknesses so that the report accurately reflects all critical aspects of the proposal.

Investigators

Discuss the competence of the principal investigator(s) and staff to conduct the proposed research, including their academic qualifications, research experiences, productivity, and any special attributes.

Resources and Environment

Describe any special aspects of the facilities and equipment, as well as the extent of departmental and interdepartmental cooperation if applicable. Comment on the reasonable availability of such resources as special animal species, tissue preparations, and clinical case material.

Budget

Discuss whether the budget is reasonable and realistic in terms of the aims and methods and whether all items are justified on the basis of the approach, procedures, and data analysis proposed. Itemize and provide specific reasons for any suggested modifications in time or amount; do not just suggest an overall cut. For supplemental requests, comment on the requested budget in relation to the approved parent budget.

Other Considerations

Research Involving Human Subjects. Safeguarding the rights and welfare of human subjects involved in research activities supported by DHHS is primarily the responsibility of the institution that receives or is accountable to DHHS for the funds awarded for support of the activity. However,

NIH also relies on its SRGs and Councils to evaluate all applications and proposals involving human subjects for compliance with human subject regulations (Code of Federal Regulations, title 45 part 46).

" 'Human subject' means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. 'Intervention' includes both physical procedures by which data are gathered (for example, venipucture) and manipulations of the subject or the subject's environment that are performed for research purposes. 'Interaction' includes communication or interpersonal contact between investigator and subject. 'Private information' must be individually identifiable, so that the identity of the subject may readily be ascertained by the investigator or associated with the information."

" 'Research' means a systematic investigation designed to develop or contribute to generalizable knowledge."

" 'Minimal risk' means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

The Department will fund research covered by the regulations only if the institution has filed an assurance with the NIH Office for Protection from Research Risks (OPRR) and has certified that the research has been approved by an institutional review board (IRB) and is subject to continuing review by the IRB. When research involves only minimal risk and meets certain other conditions, the IRB may waive the requirement for obtaining informed consent. When research is exempt from the regulations, as provided under 45 CFR 46.101(b), adherence to ethical standards and pertinent laws is still required. The initial review is expected to reflect the collective standards of the professions represented within the SRG membership.

The evaluation by SRG members will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained. Based on the evaluations of its members, the SRG may:

- recommend approval of the activity without restrictions;
- recommend approval of the activity, but record expressions of concern to be communicated to the institution and the principal investigator;
- recommend limitations on the work proposed, the imposition of restrictions, or the elimination of objectionable procedures involving human subjects;
- recommend disapproval of the application if the research risks are sufficiently serious and protection against the risks so inadequate as to consider the entire application unacceptable; or
- recommend deferral for resolution of SRG concerns for human subjects protection.

Any concerns which SRG members may wish to express regarding the adequacy of the protections afforded human subjects should be discussed in a separate paragraph entitled "Human Subjects" at the end of the "Critique." No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH. Specific concerns and policy interpretation requests may be addressed to the Office for Protection from Research Risks which is responsible for the administration and interpretation of DHHS policy and regulations for the protection of human subjects of research.

The materials listed in Appendix B may be useful guides in evaluating proposals involving human subjects.

Animal Welfare. Although the recipient institution and investigator bear the major responsibility for proper care and use of animals, NIH relies on its staff, SRGs and Councils to review research activities for compliance with the PHS policy for the care and use of vertebrate animals. Care and use of vertebrate animals in funded projects must conform to applicable law and PHS policy. The general intent of the law and policy can be summarized as two broad rules.

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists.
- Animals should not be confined, restrained, transported, cared for, and used in experimental procedures in a manner to inflict any unnecessary discomfort, pain, or injury.

Reference materials listed in Appendix B are important aids to this review of projects involving the use of animals.

For projects involving animals, the species used must be separately identified at the end of the "Description." Any concerns which SRG members may wish to express regarding the treatment and welfare of research animals used

in the project should have "Animal Welfare" as a Special Note and the Animal Welfare paragraph explaining the concerns, after the "Critique." Questions may be directed to the Office for Protection from Research Risks.

With regard to the above policies concerning human subjects protections and animal welfare, no award may be made unless the applicant institution has given the NIH Office for Protection from Research Risks an acceptable assurance of compliance with the PHS policy and all concerns or questions raised by the SRG have been resolved to the satisfaction of the NIH.

Hazardous Research Materials and Methods. The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the SRG in identifying potential hazards such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, and radioactive or explosive material.

If applications pose special hazards, these hazards must be identified and any concerns about the adequacy of safety procedures must be highlighted in the "Critique."

No awards will be made until all concerns about hazardous conditions have been resolved to the satisfaction of the NIH.

In the case of research with recombinant DNA, assessment of an applicant's compliance with DHHS guidelines is the responsibility of the NIH Office of Recombinant DNA Activites (ORDA). Although the SRG is not required to assess compliance of recombinant DNA research with NIH guidelines, an application that involves hazardous conditions should be so reported.

Reviewers' Recommendations

Reviewers may recommend that a grant application be approved, disapproved, or deferred.

Approval: Based on the relevant review criteria, the application is of sufficient merit to be worthy of support. (The specific review criteria for the major types of grants are described in a later section.) A vote for approval is equivalent to a recommendation that an award be made provided sufficient funds are available. The recommendation can be for the time and amount requested or for an adjusted time and amount. A priority rating is required.

Disapproval: The application is not of sufficient merit to be worthy of support. Disapproval may also be recommended when gravely hazardous or unethical procedures are involved, or when no funds can be recommended, such as in the case of a supplement deemed to be unnecessary. No priority rating is required.

Deferral: The SRG cannot make a recommendation without additional information. This information may be obtained by telephone, by a project site visit, or by the submission of additional material by the applicant. Deferred applications are not presented to Councils and are usually reviewed again at the next SRG meeting.

If additional information from the applicant is needed, reviewers should inform the executive secretary well in advance of the meeting to decrease chances for a deferral. Reviewers must not contact an applicant directly. All communications with applicants must be handled by the official representative of the granting agency, in this case the executive secretary of the SRG.

For some proposals, a reviewer may feel that opinions should be obtained from specially qualified experts who are not members of the SRG. Upon request, the executive secretary will seek mail opinions from other experts. Such requests should be made as promptly as possible so that outside opinions will be received in time for the meeting of the SRG.

Preliminary comments should be sent to the executive secretary's office as early as possible so that the executive secretary can read all reviews and be aware of any major difficulties or differences of opinion. Moreover, if questions have been raised, the executive secretary can often obtain answers before the meeting.

Meetings of the Scientific Review Group

SRGs normally meet three times a year for two or three days each time, depending upon the number and types of grant applications to be reviewed. A DRG study section, which is generally responsible for the review of research project grant applications, may review between 75 and 100 applications at each meeting. Each member may therefore be asked to prepare detailed written critiques on a dozen or more applications. An Institute SRG, which is usually responsible for the review of special-purpose, multidisciplinary applications, such as for program projects and centers, reviews fewer applications at each meeting. The complexity of many of these applications may, however, impose other requirements.

SRG meetings are conducted by the chairperson, who is one of the members, with assistance from the executive secretary. During the meeting, the assigned reviewers lead the discussion of the applications for which they prepared written critiques. In most instances, a consensus is reached by the group and a recommendation of approval, disapproval, or deferral is made by majority vote. Since all members will have received and are expected to have read all the applications before the meeting, they should be prepared to contribute to the discussions and to rate each favorably recommended application on the basis of their own assessments of merit.

Priority Scores

For each favorably recommended application, each member of an SRG individually and privately records a numerical rating that reflects his or her own opinion of the scientific merit relative to the "state of the art" of the proposed research. The numerical rating is based on a scale from 1.0, the best, to 5.0, the least acceptable rating, with increments of 0.1.

In rating applications recommended for approval, reviewers should:

- base their opinions strictly on thoughtful and objective considerations of the review criteria, not on emotional or budgetary considerations;
- judge the merit of each proposal independently of other proposals and according to their own standards of quality; and
- vote privately and not discuss their priority ratings with other members.

The priority rating pertains to the budget and duration of support as recommended by the SRG not requested by the applicant.

If the vote for approval is not unanimous, reviewers who recommend disapproval must also record a priority rating, which may, but need not be, 5.0. If a reviewer recommending disapproval does not assign a priority rating, the staff will record a vote of 5.0, unless the reviewer elects to abstain and so indicates on the voting worksheet.

After the meeting, the executive secretary averages the individual reviewers' ratings for each favorably recommended application and multiplies by 100 to provide a three-digit rating that is the priority score. Priority scores are included in summary statements, which are forwarded to the Institutes for Council review and then to the principal investigators after completion of the peer review process.

Priority scores guide the Councils and Institutes in their decisions about the order in which approved applications are funded. Although Councils may not change priority scores, they may recommend—usually on the basis of high or low "program relevance"—whether an approved application should be funded. Nevertheless, even when program interests determine financial support for a project, the priority score usually influences the final decision about funding.

Site Visits

For the review of some applications, information needed to make a recommendation can be gathered only at the proposed research or training site. When such a situation arises, a site visit is planned. Site visits may occur either before the meeting of the SRG, if an assigned reviewer or the executive secretary recognizes the need for additional information that cannot be obtained by mail or telephone, or after a formal deferral action at the meeting of the SRG, if the group is unable to reach a conclusion on the basis of the information available at their meeting. In addition, site visits are often desirable when the application involves complex coordination, as with many applications for program project or center grants, or when the educational and research environment must be assessed, as with many applications for research training grants.

In each case, the executive secretary assembles a team of site visitors who are charged with gathering information on specific aspects of the proposed project and reporting their findings and recommendations to the SRG at its next meeting. For a research project grant application (R01), the site visit team generally includes two or more members of the SRG, the executive secretary, and a member of the Institute staff, and may also include ad hoc consultants who are experts in critical aspects of the proposed work. For more complex grant applications, such as for program project or center grants, a larger site visit team may be needed. During the site visit, the site visitors meet with the principal investigator and any other personnel considered central to the proposal and discuss the areas in question, such as specific procedures, facilities, and administrative arrangements. The report of the site visit team serves as the basis for discussion of the application at the next meeting of the SRG. This discussion is led by the SRG members who attended the site visit.

Summary Statements

Immediately after the meeting of the SRG, the executive secretary prepares a summary statement for each application. These summary statements, which are based on a combination of the reviewers' written comments and the discussion by the SRG during the meeting, become the official documents describing the deliberations of the SRG.

Summary statements include the recommendations of the SRG, a recommended budget, and notations of any special points, such as a potentially hazardous experimental procedure. A separate minority critique must also be provided if two or more members of an SRG voted against the majority recommendation. Individual reviewers' written comments and other notes are not retained after the summary statements have been prepared.

Summary statements have numerous and important uses.

- Council members use summary statements as the main source of information about applications and as the primary basis for their recommendations.
- Institute staff use summary statements as a basis for discussions with Councils and as guides in the future management of the resulting grants.
- After Council meetings, Institute staff send each principal investigator a copy of the summary statement with the priority score displayed. The summary statement is therefore important to investigators in reassessing, adjusting, or improving their research projects, as well as in preparing future applications.
- Summary statements, whenever appropriate, can provide background information to SRGs relative to a revised, supplemental, or competing continuation application submitted in the future.

Initial Review of Applications for Major Types of Grants

The previous section described *general* procedures that apply to the initial review process for scientific and technical merit. There are, however, special considerations for the review of each type of grant application. These specific considerations for some of the major grant mechanisms are described in this section. (Information about these and other forms of support, such as center grants and resource grants, is available from the executive secretary.)

Research Project Grant (R01) Applications

Objective

The objective of the research project grant is to support a discrete, specified project in an area representing the interests and competency of a principal investigator, who is designated by the applicant institution and who may be assisted by or collaborate with other investigators.

Initial Review

Most research project grant applications are reviewed for merit by study sections in the DRG. In some cases, such as for applications received in response to a formal solicitation, the DRG may delegate the initial review to a review group organized by the sponsoring Institute.

Review Criteria

The principal criteria for the initial review of applications for research project grants include:

- scientific, technical, or medical significance and originality of the proposed research;
- appropriateness and adequacy of the experimental approach and methods to be used;
- qualifications and experience of the principal investigator and staff in the area of the proposed research;
- reasonable availability of resources necessary to the proposed research;
- reasonableness of the proposed budget and duration in relation to the proposed research; and
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Site Visits

The review of research project grant applications may on rare occasions require a project site visit, usually in response to deferral of the application by the SRG for that purpose.

A project site visit is recommended only when the review group must obtain information that cannot be communicated satisfactorily through correspondence or by telephone. Usually, such information relates to specific details about the scientific aspects of the proposed project; the arrangements for collaboration; the progress during a previous project period; or the departmental or institutional interest, commitment, support, and plans in relation to the personnel and the project. In some cases, the SRG may need to observe an experimental technique or preparation or assess the appropriateness of special equipment and procedures that are essential to the conduct of the proposed research.

The site visit team customarily includes a small number of consultants, the executive secretary in charge of the review, and a representative from the awarding Institute. Members of the SRG are preferred as consultant visitors because they can discuss the visit and answer questions at the next meeting of the SRG. In many cases, the visitors include ad hoc consultants with special competence in some unusual, but critical, aspect of the proposed investigation.

Site visits for the review of research project grant applications seldom last more than a day. The principal activity is a detailed but informal discussion of objectives, methods, and procedures. A report of the site visit provides the basis for arriving at a recommendation at the next meeting of the SRG.

New Investigator Research Award (R23) Applications

Ojective

The objective of the New Investigator Research Award (NIRA) is to encourage new investigators in basic or clinical science disciplines, including those who have interrupted early promising research careers, to develop their interests and capabilities in biomedical and behavioral research.

Initial Review

The initial merit review of NIRA applications is by study sections in the DRG.

Review Criteria

The review criteria for the initial review of NIRA applications are the same as for research project grant applications, except that a principal investigator for a NIRA is less likely to be able to submit an application in the same breadth and depth as an experienced investigator. Also in the evaluation of the qualifications and experience of the principal investigator, the emphasis is on evaluating the individual's background as a guide to future development into a creative, independent investigator.

Site Visits

The review of NIRA applications occasionally requires a project site visit. The procedures are the same as for research project grant applications.

Program Project Grant (P01) Applications

Objective

The objective of the program project grant is to support a broadly based, multidisciplinary, often long term-research program that has a well-defined, overall major goal or basic theme. The individual component projects must have scientific merit and the essential elements of unity and interdependence that constitute a system of research activities and projects directed toward the overall goal of the program.

Initial Review

Applications for program project grants are reviewed for scientific and technical merit by SRGs maintained or organized for that purpose by the Institutes. In some cases, the initial review is conducted by special study sections in the DRG.

Review Criteria

The initial review for scientific and technical merit emphasizes two major aspects of the program project grant application: each component project and core unit, and the program as an integrated research effort focused on a central theme.

Review of Projects and Core Units. The review criteria include:

- scientific merit of each research project and the relation of the project to the central theme of the overall program;
- technical merit of and justification for each core unit;
- accomplishments and progress of the projects and core units to date for competing continuation (renewal) and supplemental applications;
- qualifications, experience, and commitment of the investigators responsible for the research projects or core units and their ability to devote adequate time and effort to the program;
- appropriateness of the budget for the proposed projects and core units; and,
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Review of the Program as an Integrated Effort. The review criteria include:

- significance and importance of the research program to the overall goal or theme of the program;
- appropriateness of the central theme of the proposed program as a feasible approach for a cooperative research effort;
- multidisciplinary scope of the program and the coordination and interrelation of the research projects and core units;
- leadership and scientific stature of the program director and the commitment and ability to devote adequate time and effort to the program;
- participation of an effective number of responsible, experienced investigators;
- academic and physical environment in which the research would be conducted, including the availability of space, equipment, patients, and the potential for interaction with scientists from other departments and other institutions;
- arrangement for internal quality control of ongoing research, the allocation of funds, day-to-day management, internal communication and cooperation between the investigators involved in the program, and contractual agreements;
- presence of an administrative and organizational structure that would facilitate attainment of the proposed objective of the program;
- institutional commitment to the requirements of the program; and
- appropriateness of the budget to the proposed program.

Site Visits

The review of an application for a program project grant often includes a site visit because of the complexity and multidisciplinary characteristics of this type of grant. Program project grant applicants are usually visited before the applications are considered by the SRG.

The initial review for the scientific and technical merit of a program project grant application may be by a review group, which would be formed for that particular purpose and which might also function as the site visiting team, or by a standing committee. In the latter case, the executive secretary would send representatives from the standing committee and additional consultants on the project site visit.

During the site visit, the site visitors meet with the program director, the principal investigators of all the component projects and core units, and the applicant institution's key administrative officials. Site visits for the review of a complex program may require two or three days for the review of all the components of the proposed program.

The results of the site visit are documented in full detail in a report in which the site visitors make recommendations to the parent SRG. The SRG uses the information obtained at the site visit in arriving at a recommendation, and the executive secretary usually incorporates the site visit report into the summary statement.

Instructions for the Preparation of Applications

Several of the Institutes have prepared pamphlets to assist potential principal investigators in the preparation of program project applications. These documents, which are available from the Institutes, may be helpful to new SRG members.

National Research Service Award Applications

Postdoctoral Fellowship (F32) Applications

Objective

The objective of the National Research Service Award (NRSA) postdoctoral fellowship is to provide those who hold doctorate degrees with additional research training that will broaden their scientific background and extend their potential for research in specified health-related areas.

Initial Review

The initial review of applications for postdoctoral fellowships is conducted by study sections or ad hoc review groups in the DRG. (The initial review of these applications rarely, if ever, involves a project site visit.)

Review Criteria

The principal criteria for the initial review of applications for postdoctoral fellowships include:

- candidate's academic background, awards and honors (including professional societies), prior research experience, prior professional training, and publications, as well as the candidate's references and research competence and potential;

- quality of the training resources and environment, especially the suitability of the sponsor and department;
- relationship of the additional training to the candidate's background and future objectives;
- strengths and weaknesses of the research proposal, including the training value of the proposal and its relationship to the sponsor's research effort; and
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Senior Fellowship (F33) Applications

Objective

The objective of the NRSA senior fellowship is to provide opportunities for experienced scientists to make major changes in the direction of their research careers, to broaden their scientific background, to acquire new research capabilities, or to enlarge their command of an allied research field.

Initial Review

The initial review of applications for senior fellowships is conducted by study sections or ad hoc review groups in the DRG. (The initial review rarely, if ever, involves a project site visit.)

Review Criteria

The principal criteria for the initial review of applications for senior fellowships are the same as for postdoctoral fellowships, except that the emphasis is on the candidate's research competence rather than research potential.

Institutional Training Grant (T32) Applications

Objective

The objective of the NRSA institutional training grant is to enable institutions to provide research training to predoctoral or postdoctoral fellows they select.

Initial Review

The initial review of applications for institutional training grants is conducted by SRGs in the Institutes.

Review Criteria

The principal criteria for the review of an application for an institutional training grant include:

- qualifications, productivity, and research training experience of the participating faculty;
- proposed research training objectives and program design;
- previous training record of the program, including the ability to attract the most promising students and the success such students subsequently achieved;
- institutional commitment to the training program;
- facilities and environment;
- relation of the proposed program goals to the need for research personnel; and,
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Site Visits

The review of an application for an institutional training grant may include a site visit. The format is adapted to satisfy the review criteria above and usually includes interviews with students as well as with members of the faculty.

Research Career Development Award (K04) Applications

Objective

The objective of a Research Career Development Award (RCDA) is to foster the development of scientists who have demonstrated outstanding research potential for independent research careers in the health-related sciences.

Initial Review

The initial review of RCDA applications is conducted by study sections in the DRG.

Review Criteria

The principal criteria for the review of RCDA applications include:

- adequacy and appropriateness of the candidate's training;
- significance and originality of the candidate's previous research experience and proposed research;
- candidate's potential for becoming an independent investigator as evidenced by relevant factors, including at least two letters of recommendation;
- institutional commitment to fostering the research career of the candidate, as reflected in the statement of commitment from the sponsoring official, the extent to which the candidate will be relieved of other academic responsibilities to provide additional time for research, and the provision of laboratory facilities and equipment; and,
- where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Site Visits

The review of an application for an RCDA occasionally involves a project site visit, the format for which is similar to that for the review of a research project grant (R01) application.

Review by National Advisory Councils and Boards

The second level review for grant applications is by the Councils, which assess the quality of the SRG scientific merit reviews, consider the relevance of the proposed research to the Institute's programs and priorities, and advise on Institute policy. Councils may concur with or modify recommendations from an SRG. When there is disagreement about scientific merit, the application is usually returned for additional review by the same or by a different SRG.

With the exception of individual fellowship applications and some grant applications recommended at direct costs not exceeding $35,000 annually (in the National Cancer Institute and the National Heart, Lung, and Blood Institute), grants can not be awarded without recommendations for approval by a Council.

4. Review Process: Contract Proposals

The majority of contract proposals are in response to a published, solicited request for proposals (RFP); unsolicited contract proposals are only rarely accepted by the NIH. For the purpose of this handbook, the following discussion is limited to the review process for a solicited contract project. This review process begins with the preparation of an RFP and concludes with the Institute awarding contracts to one or more offerors (Figure 7).

Concept Development and Review

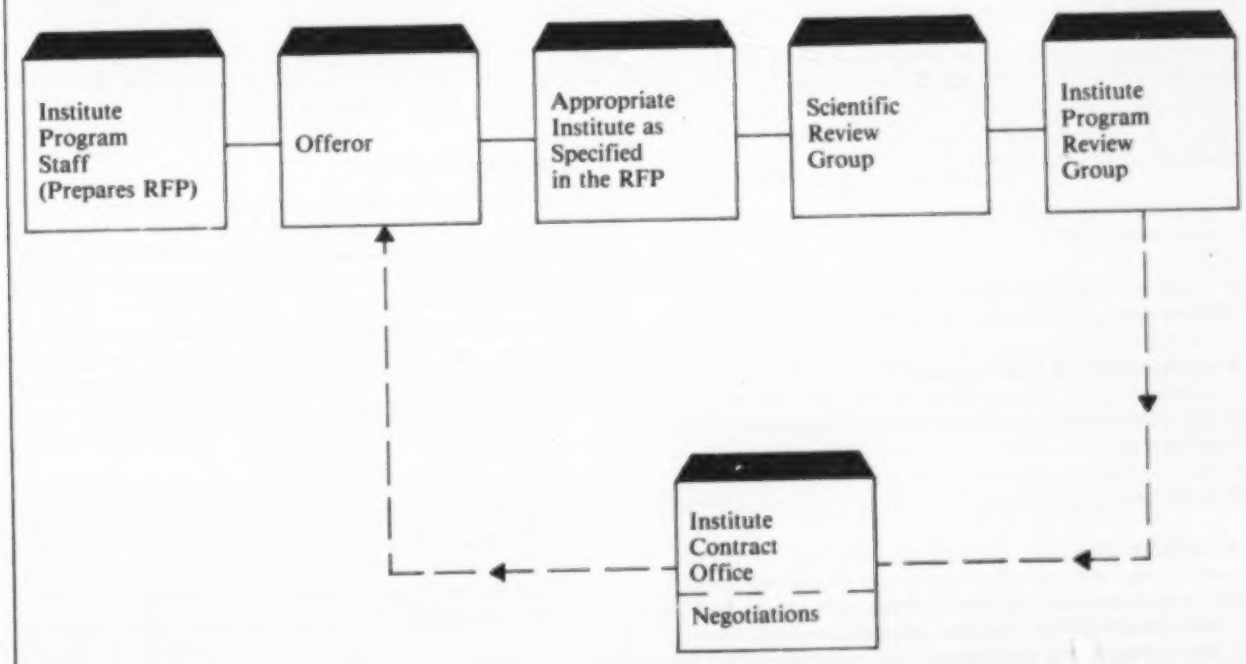
The idea for a contract can come from many sources, such as congressionally mandated directives, Institute staff initiatives, or ideas received from the scientific community. A contract is appropriate when the facilities, staff, or special skills required to procure a specific service or product are not available in the Institute; or when there is a need for a number of institutions to participate in a collaborative project for which the Institute will provide a high degree of guidance.

Once Institute staff determine the need for a contract, the concept and technical approach for the proposed project must be reviewed by an Institute peer review group, usually a program advisory committee. As a courtesy, or sometimes because of statutory requirements, an Institute may also present the concept for a proposed contract-supported project to the Council for review. A formal solicitation document, the RFP, is then prepared.

Request for Proposals

The RFP specifies the terms, conditions, and provisions for the requested contract. RFPs are announced in the *Commerce Business Daily* as required by law, in the *NIH Guide for Grants and Contracts* as required by policy, in other appropriate publications as determined by program requirements, and in announcements to investigators on Institute mailing lists. Competition is encouraged to the maximum practical extent as required by the laws that govern Federal procurement procedures.

Figure 7.
Initiation and Review of a Solicited Contract Proposal



Scientific Review by Peers

An Institute SRG or an ad hoc group is usually responsible for the scientific and technical review of proposals received in response to an RFP.

Reviewers' Preliminary Written Comments

The process for the scientific review of contract proposals is similar to that for grant applications. The executive secretary sends the reviewers copies of all the proposals to be reviewed at the meeting of the SRG. Each member is expected to read the entire set of proposals and to be prepared to participate in the discussion at the meeting. In addition, the executive secretary designates principal or lead reviewers for each proposal. These designated reviewers prepare written comments about their assigned proposals and lead the discussion about the proposals during the meeting of the SRG.

Meetings of the Scientific Review Group

The executive secretary of the SRG is in charge of the review meeting, and the project officer and contract specialist are responsible for providing any necessary background information and for answering any questions about the RFP.

Review Criteria

The evaluation criteria for the scientific and technical review of contract proposals are formulated by the Institute to match the specific requirements of the RFP and are listed in the RFP. Typical review criteria may include consideration of such factors as:

- proposer's understanding of the goals and scope of the work solicited;
- proposed method for assuring the timely and acceptable performance of the required work;
- compliance with requirements of the RFP;
- competence of the professional and technical personnel;
- technical organization;
- facilities; and
- where a proposal involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

Recommendations and Scores

When the discussion of the proposals has been completed and the strengths and weaknesses of each proposal have been thoroughly examined, the executive secretary requests every member of the SRG to rank each proposal, to assign each proposal a rating score based on the specific evaluation criteria, and to categorize each proposal as acceptable or unacceptable. These recommendations form the basis for the proposal evaluation report that is transmitted to the Institute program committee for the next level of review.

Site Visits

Occasionally a site visit may be necessary for inspection and evaluation of the proposers' facilities as well as for discussions with scientific and technical staff. Such a visit may either be recommended by the SRG or decided upon by the contracting officer.

Summary Statements

After the primary technical review has been completed, the executive secretary prepares a proposal review summary, which is maintained as a permanent record in the official files. This summary statement, which is analogous to that for grant applications, describes the evaluation for each proposal, particularly the strengths and weaknesses for each of the review criteria, and identifies any qualifications that may bear upon the selection of proposals for negotiation and award. The official proposal review summary is forwarded for use by the appropriate Institute program committee in the next level of review.

Program Review

The program review for contract proposals is performed by a committee of senior Institute scientific and contract staff. Their decisions are based on the recommendations of the SRG, subsequent reviews of revised proposals, program balance, cost, availability of funds, and the proposed means for protecting against any potentially adverse effects upon humans, animals, or the environment.

5. Review-Related Issues

Standards of Conduct

Conflict of Interest

When a member of an SRG or the member's spouse, parent, child, partner, or close professional associate is named in a grant application as the principal investigator, or as an investigator who is currently, or expected to be, responsible for conducting a project, the SRG on which the investigator is a member may not review the application. Instead, the Referral Office, DRG, or the Institute (in the case of an Institute review) arranges to have the application evaluated by another SRG.

Members and reviewers must leave the meeting room when applications submitted by their own organizations are being discussed. In the case of state higher education or other systems with multiple campuses geographically separated, the term "own organization" is intended to mean the entire system where the member or reviewer is an employee, consultant, officer, director or trustee, or has a financial interest. The entire system for a state university includes all the campuses and other state institutions which may be part of the same legal entity.

In addition, members and reviewers should be urged to avoid any actions that might give the *appearance* that a conflict of interest exists. Thus, for example, a consultant should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Another example might be an application from a scientist with whom the member or reviewer has had long-standing differences which could reasonably be viewed as affecting the consultant's objectivity.

For the review of contract proposals, no one who has submitted a proposal or is from an institution submitting a proposal may participate as a member of the SRG that reviews these proposals.

At the end of a meeting of an SRG, the executive secretary obtains written certification from all consultants that they have been absent from and have not participated in any reviews of proposals or applications where their presence would involve a conflict of interest (Appendix C).

Before appointment to an SRG and annually during the term of service thereafter, each member completes form HEW 474, "Confidential Statement of Employment and Financial Interests." Members of SRGs are considered "special government employees" in terms of DHHS standards of conduct and for determining conflict-of-interest situations.

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of SRGs are requested to leave all review materials with the executive secretary at the conclusion of the site visit or review meeting.

Under no circumstances should consultants advise applicants of recommendations or discuss the review proceedings with them. Premature advice to the applicant may prove embarrassing to all concerned and be a distinct disservice to the applicant, who may be led into unwise actions on the basis of erroneous information. Premature notification of recommendations to applicants before the review has been completed often leads to misinterpretation and distortion of the discussions of review groups, represents an unfair intrusion into the privileged nature of the proceedings, and invades the privacy of fellow consultants serving on review committees and site visit teams. A significant result of such a breach of confidentiality could be to deter qualified consultants from serving on review committees and to inhibit those who do from engaging in free and full discussion of recommendations. The protection of the confidentiality of review proceedings is in the best interest of the highly respected peer review system used by the NIH and the NIH tradition of allocating public funds on the basis of research excellence.

Communications with Applicants

There should be *no* direct communications between members of SRGs and applicants. All communications are handled by the executive secretary of the SRG. Telephone inquiries and correspondence from applicants should be referred to or sent to the executive secretary.

Privacy Act

Under the Privacy Act, principal investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports, summary statements, and reviewers' written comments, if available. Reviewers' written comments, however, are not retained after their substance has been incorporated into summary statements or site visit reports.

A reviewer may choose whether to sign review comments. If review comments that identify the reviewer have to be made available to a principal investigator, the reviewer will be promptly notified by the Institute or DRG staff.

Open and Closed Portions of Meetings

All Federal advisory committee meetings are open to the public under the provisions of the Federal Advisory Committee Act. All discussions related to the reviews of grant applications and contract proposals, however, are closed to the public under exemptions of the Government in the Sunshine Act (Public Law 94-409).

Consultant Expenses and Reimbursement

Allowable consultant expenses are round trip air transportation, ground transportation, and per diem costs, which can vary according to location. A consultant fee is paid to each participant in an SRG for each day or fraction of a day spent on a site visit or at a meeting of a review group.

Consultants are asked to make their own transportation arrangements and to purchase their own airline tickets. Travel should be by the most direct route. Any additional costs resulting from indirect routing or stopovers should be waived or explained if reimbursement is claimed. When air transportation is used, travelers are expected to use less than first-class accommodations.

Reimbursement forms (Appendix C) will be distributed by the executive secretary before or during the meeting. Reviewers are asked to include Social Security numbers and home addresses to ensure prompt processing and reimbursement of the expenses and fees associated with the trip.

Appendix A. Peer Review Bibliography

Bondurant, S. Peer review of research project grants by NIH study sections. Report of the Committee on National Medical Policy, American Society for Clinical Investigation. *Clinical Research* 25:297-305, 1977.

Eaves, G.N. Who reads your project-grant application to the National Institutes of Health? *Federation Proceedings* 31:2-9, 1972.

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Eaves, G.N. The grant application: an exercise in scientific writing. *Federation Proceedings* 32:1541-1543, 1973.

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Gee, H.H. Preparation of the project-grant application: assistance from the administrator in charge of a study section. *Federation Proceedings* 32:1544-1545, 1973.

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Malone, T.E. Preparation of the project-grant application: assistance from the institutes and other awarding units. *Federation Proceedings* 32:1546-1547, 1973.

Merritt, D.H. Grantsmanship: an exercise in lucid presentation. *Clinical Research* 11:375-377, 1963.

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Pike, J.M., and Bernard, S.C. The research grant budget: preparation and justification in relation to the proposed research. *Grants Magazine* 1:283-286, 1978.

Rifkin, D.B. A beginning scientist's first project-grant application. *Federation Proceedings* 32:1543, 1973.

Ross, R. Participation of the administration of the grantee institution in the preparation and transmission of a project-grant application. *Federation Proceedings* 32:1547-1548, 1973.

Schimke, R.T. Preparation of the project-grant application: assistance from the grantee institution's experienced investigators. *Federation Proceedings* 32:1548-1550, 1973.

United States, Department of Health, Education, and Welfare, National Institutes of Health, Grants Peer Review Study Team. *Grants Peer Review: Report to the Director, NIH, Phase I,* Volumes I, II, and III, December 1976, and Phase II, December 1978. (No DHEW publication number.)

United States, Department of Health, Education, and Welfare, National Institutes of Health, Subcommittee on the Survey of the Grant Peer Review System. *Survey of the NIH Grant Peer Review System: Analysis of Survey Responses and Comments,* July 1, 1977. (No DHEW publication number.)

Appendix B. Bibliography on Research Involving Human Subjects and Animal Welfare

Research Involving Human Subjects

Code of Federal Regulations, Title 45, Part 46, as amended.

Cumulative List of Institutions in General Compliance with HHS Regulations. (Issued periodically by the Office for Protection from Research risks.)

NIH Manual Issuance 4107, Review of Applications and Award of Grants Involving Human Subjects (Currently being updated.)

NIH Manual Issuance 6000-3-4.55, Contracts Involving Human Subjects (Currently being updated.)

PHS Act, Title IV, Section 474. (42 U.S.C. 2891-3)

PHS Grants Administration Manual Chapter 1-40, Protection of Human Subjects.

Public Law 93-348, Title II, Protection of Human Subjects of Biomedical and Behavioral Research. (42 U.S.C. 2891-1)

Animal Welfare

Code of Federal Regulations, Title 41, Chapter 3, Subpart 3-4.58, Procurements Involving the Use of Laboratory Animals.

Guide for the Care and Use of Laboratory Animals, DHEW No. (NIH) 78-23 (revised 1978 or succeeding editions).

NIH Manual Issuance, 4206 and 6000-3-4.58, Responsibility for Care and Use of Animals.

PHS Grants Administration Manual Chapter 1-43, Animal Welfare.

Public Law 89-544, 1966, amended in 1970 and 1976.

NOTE: Copies of the above documents are available from your Executive Secretary.

Appendix C. Sample Forms

Certification of No Conflict of Interest

This will certify that in the review of applications and proposals conducted by the _____ on _____, I absented myself from the room during the review of any application from an organization, institution, or university system where I am an employee, consultant, officer, director or trustee, or have a financial interest. I was not present during the review of any application or proposal when my presence would have constituted a real or apparent conflict of interest.

(Signature and Typed Name)	(Signature and Typed Name)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Reimbursement Form

IMPORTANT

NIH MUST REPORT TO IRS AS OF DECEMBER 31, 1976 ALL EXPENSES PAID TO INDIVIDUAL CONSULTANTS. THE AMOUNT NIH WILL BE REPORTING WILL INCLUDE CONSULTANT FEE, TRAVEL, AND PER DIEM. YOU SHOULD BE SURE TO RETAIN A COPY OF THE REIMBURSEMENT CLAIM FOR USE IN PREPARING YOUR INCOME TAX SINCE ONLY THE CONSULTANT FEE AMOUNT IS TAXABLE.

THE FOLLOWING ADDITIONAL INFORMATION IS NOW REQUIRED BY THE NIH. PLEASE COMPLETE THESE FORMS AND RETURN THEM PROMPTLY TO EXPEDITE REIMBURSEMENT.

NAME _____

SS# _____

HOME ADDRESS _____

THANK YOU FOR YOUR COOPERATION.

Submit in TRIPLICATE. Please read carefully, including information on reverse.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH

CLAIM FOR REIMBURSEMENT OF TRAVEL COST, PER DIEM, AND CONSULTANT FEE

DATE

NAME OF CHAIRMAN

STUDY SECTION, REVIEW GROUP OF COMMITTEE

PLACES AND DATES OF ASSIGNMENT

TRAVEL ITINERARY

NOTE: In cases of combined personal and official business during the same trip, show departure and return time that could have been followed for the sole purpose of this assignment. Take this into account in itemizing expenses below.

LEFT (City, date, hour)

RETURNED (City, date, hour)

DATE OF MEETING(S) OR SITE VISIT(S)

TRAVEL EXPENSES

(A) Cost of transportation (receipts required). If mixed mode of travel, indirect routing, or stopovers for personal reasons are involved, claim only cost of usual direct-route round trip fare. If travel is by privately owned plane, 24¢ an air mile is allowed; or by private auto, _____¢ a mile (not to exceed cost by common carrier) will be allowed.
Speedometer Readings:

$

(B) Taxi or limousine used for official business, including up to 15% for tips. (Receipts not required.)

$

(C) Other (Examples - Road and bridge tolls, parking, telegram and telephone calls for official business, conference room rentals.) Receipts required only on items costing $15 or more. Flight or other travel insurance is considered a personal expense and is not reimbursable.

Identify claims:

$

(D) TOTAL TRAVEL EXPENSES →

(E) Lodging: Itemize each day's meal and lodging costs (including tax). This information is needed to determine the appropriate per diem allowance under the "Lodging Plus" system, and the "Actual Expense" method. (See reverse)

DAY	DATE	LODGING	BREAKFAST	LUNCH	DINNER	TOTAL
1ST		$	$	$	$	$
2ND						
3RD						
4TH						
5TH						

If unusual circumstances regarding an assignment affect your claim, check this block and explain on reverse side in REMARKS. ☐

STATEMENT OF PERSONAL SERVICES

I certify that the above itemization reflects costs incurred for official business and that I provided consultant services in connection with this assignment on the dates indicated.

HOME ADDRESS

ADDRESS (Where check is to be mailed if other than home)

SOCIAL SECURITY NO. (See Privacy Statement on reverse)

SIGNATURE OF CONSULTANT

THIS SECTION FOR NIH USE ONLY

1. I certify that the above Consultant is entitled to a consultant fee for_____days at $100 per day. $

Signature of Executive Secretary:

2. Per diem_____days at $_____per day and/or Actual & Necessary (as determined by Item E) $

3. Travel (from Item D, above) $

ADVANCE DEDUCTED (When Applicable)

4. TOTAL TO BE PAID → $

Pre-audited by

Approved by

043260

NIH -1715-2 (FRONT) REV. 12-79

CARBON PAPER NOT REQUIRED BETWEEN PARTS WHEN WRITING ON THIS SIDE